



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-6266]

#### Request for Nominations on the Pediatric Advisory Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Pediatric Advisory Committee for the Office of the Commissioner notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Pediatric Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. (See sections I and II of this document for further details.) Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Shivana Srivastava (see FOR FURTHER INFORMATION CONTACT). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal:

<https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to

Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Shivana Srivastava, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5157, Silver Spring, MD 20993, 301-796-8695, email: [Shivana.Srivastava@fda.hhs.gov](mailto:Shivana.Srivastava@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add a nonvoting industry representative(s) to the Pediatric Advisory Committee:

#### I. General Description of the Committee Duties

The Committee reviews, evaluates, and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding (1) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act (42 U.S.C. 262, 284m, and 290b) and sections 501, 502, 505, 505A, 505B, 510(k), 515, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m)); (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices; (4) pediatric labeling disputes as specified in Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (5) pediatric labeling changes as specified in Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (6) adverse event reports for drugs studied under Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (7) any safety issues that may occur as specified in Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products; (9) pediatric ethical issues

including research involving children as subjects as specified in 21 CFR 50.54; and (10) any other matter involving pediatrics for which FDA has regulatory responsibility.

The Committee also advises and makes recommendations to the Secretary of Health and Human Services (the Secretary) (HHS) directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by HHS as specified in 45 CFR 46.407.

## II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

## III. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current resume, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see ADDRESSES) within 30 days of publication of this document (see DATES). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of individuals on its advisory committees regardless of their gender identification, religious affiliation, racial and ethnic identification, or disability status and therefore encourages nominations of appropriately qualified candidates from all groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 22, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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